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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,616	01/22/2004	Luisa Hernandez-Ramirez	91349	5023

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EXAMINER	
SIMMONS, CHRIS E	
ART UNIT	PAPER NUMBER
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/762,616	HERNANDEZ-RAMIREZ ET AL.	
	Examiner	Art Unit	
	CHRIS E. SIMMONS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6,13 and 15-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,13 and 15-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 6/12/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/12/2009 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 13, 15, 17, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0130225 in view of Wallin et al. (Br. J. Vener. Dis. (1974);50;148-150).

The primary reference discloses anti-infection agents utilized in the compositions and methods of the invention that may be selected from an antifungal, an anti-bacterial, an anti-viral, a probiotic agent or a combination thereof [0058]. The reference discloses an oral medication comprising fluconazole, which may be taken to treat a skin fungal infection with an approved dose such as about 150 mg or at a lower dose [0021]. Other antimicrobials may be present in the composition such as secnidazole or tinidazole [0027]. The medicament should be included in a composition containing a pharmaceutically-effective amount of the active ingredient in a pharmaceutically

acceptable carrier. The medicament may be administered in one or more doses. If administered in more than one dose, the dosage level of active ingredient in the medicament may be the same in each dose, or may be first administered in a higher level or bolus and then in a lower maintenance dose [0018]. The reference does not expressly teach the fluconazole and tinidazole in a single dosage unit or the claimed concentrations for tinidazole or secnidazole.

The secondary reference discloses of secnidazole and 2 grams and 1.6 grams of tinidazole are effective antimicrobials at 2 grams each (also 1.6 grams for tinidazole) (p. 150, *Summary)*. The reference does not expressly teach a single unit dosage of fluconazole and tinidazole or the claimed concentrations in claims 3, 13 and 17-22.

It would have been obvious to add the tinidazole from the secondary reference to the composition containing fluconazole in the primary reference. The motivation would have been the reasonable expectation of success since both the agents are disclosed in each reference as antimicrobials that are useful for treatment of vaginal infections. See MPEP 2144.05. It would have been obvious to one of ordinary skill in the art to make a single tablet containing a mixture of fluconazole and tinidazole. Motivation for doing so would be to make a single tablet containing fluconazole and tinidazole for easier administration since both ingredients can be taken as one single tablet instead of several tablets. Decreasing the amounts would aid to minimize the size of the tablet for easier administration.

With respect to the amounts in claims 3, 13, and 17-22, it would have been obvious to alter the amounts of fluconazole and tinidazole to 112.5 mg and 1.5 g,

respectively, for example. Fluconazole is disclosed in the primary reference to have approved doses such as about 150 mg which can be lowered or increased. If administered in more than one dose, the dosage level of active ingredient in the medicament may be the same in each dose, or may be first administered in a higher level or bolus and then in a lower maintenance dose. The disclosure gives the artisan motivation to adjust the amounts of ingredients to optimize the amounts. Accordingly, these differences in claimed amounts from the prior art amounts are not enough to make the claimed patentable over the prior art.

Claims 2, 3, 5, 18, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0130225 in view of Videau et al. (Br. J. Vener. Dis. (1978);54;77-80).

The disclosure of the primary reference is disclosed above. The reference does not expressly teach the fluconazole and secnidazole in a single dosage unit or the claimed concentrations for tinidazole or secnidazole.

The secondary reference discloses that 2 grams of secnidazole are effective for the antimicrobial treatment of vaginal infection (p. 78, *Table 1)*. The reference does not expressly teach a single unit dosage of fluconazole and secnidazole or the claimed concentrations in claims 3, 13 and 17-22.

It would have been obvious to add the secnidazole from the secondary reference to the composition containing fluconazole in the primary reference. The motivation would have been the reasonable expectation of success since both the agents are

disclosed in each reference as antimicrobials that are useful for treatment of vaginal infections. It would have been obvious to one of ordinary skill in the art to make a single tablet containing a mixture of fluconazole and secnidazole. Motivation for doing so would be to make a single tablet containing fluconazole and secnidazole for easier administration since both ingredients can be taken as one single tablet instead of several tablets. Decreasing the amounts would aid to minimize the size of the tablet for easier administration.

With respect to the amounts in claims 3, 13, and 17-22, it would have been obvious to alter the amounts of fluconazole and secnidazole to 112.5 mg and 1.5 g, respectively, for example. Fluconazole is disclosed in the primary reference to have approved doses such as about 150 mg which can be lowered or increased. If administered in more than one dose, the dosage level of active ingredient in the medicament may be the same in each dose, or may be first administered in a higher level or bolus and then in a lower maintenance dose. The disclosure gives the artisan motivation to adjust the amounts of ingredients to optimize the amounts. Accordingly, these differences in claimed amounts from the prior art amounts are not enough to make the claimed patentable over the prior art.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0130225 and Videau et al., the combination taken in view of USP 5,660,860.

The disclosure of the primary and secondary references and the rationale for their combination are outlined above. The references do not expressly disclose the vehicle ingredients in the claim.

The tertiary reference discloses optionally coated water-dispersible tablets to provide a tablet which is capable of dispersing in water within 3 minutes. The composition comprises inert ingredients such as microcrystalline cellulose, sodium glycolate of starch, polyvinylpyrrolidone, magnesium stearate and white opadry (abstract; claim 16). The reference does not disclose fluconazole and secnidazole.

It would have been obvious to one of ordinary skill in the art to add the vehicle ingredients in the tertiary reference to the fluconazole and secnidazole composition suggested by the other references. The motivation for doing so would have been the desire to make a water dispersible tablet which is capable of dispersing in water within a short period of time.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0130225 and Wallin et al., the combination taken further in view of USP 5,660,860.

The disclosures and the rationale for the combination of the primary and secondary references are outlined above. The references do not expressly disclose the vehicle ingredients in the claim.

The tertiary reference discloses optionally coated water-dispersible tablets to provide a tablet which is capable of dispersing in water within 3 minutes. The

composition comprises inert ingredients such as microcrystalline cellulose, sodium glycolate of starch, polyvinylpyrrolidone, magnesium stearate and white opadry (abstract; claim 16). The reference does not disclose fluconazole and tinidazole.

It would have been obvious to one of ordinary skill in the art to add the vehicle ingredients in the tertiary reference to the fluconazole and tinidazole composition suggested bu the other references. The motivation for doing so would have been the desire to make a water dispersible tablet which is capable of dispersing in water within a short period of time.

Conclusion

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. E. S./
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612